

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant: Joel R. Studin   | Art Unit: 1615              |
| Serial No: 10/829,316   | Examiner: Sheikh, Humera N  |
| Filing Date: April 21, 2004   |                             |
| Title: <i>Method and Composition<br/>for the Treatment of Scars</i> | Atty. Docket No.: SDF 04-14 |

**REPLY BRIEF**

Commissioner of Patents  
and Trademarks  
P.O. Box 1450  
Alexandria, VA 22313-1450

Madam:

This is a Reply Brief in response to the Examiner's Answer dated May 13,  
2009, relative to the above-identified application.

STATUS OF THE CLAIMS

Claims 1-16 and 30-32 have finally been rejected and are the subject of this appeal. Claims 17-29 and 33-54 have been cancelled.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

(1) *Whether the Examiner properly rejected claims 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Youssefyeh et al. (U.S. Pat. No. 5,968,519) in view of Lee (U.S. Pat. No. 5,552,162); and*

(2) *Whether the Examiner properly rejected claim 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Lee (U.S. Pat. No. 5,552,162).*

ARGUMENT

(1) **Whether the Examiner properly rejected claims 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Youssefyeh et al. (U.S. Pat. No. 5,968,519) in view of Lee (U.S. Pat. No. 5,552,162).**

Appellant has argued at page 5 of the Appeal Brief that the treatment of scarring as claimed is not equivalent to the treatment of the inflammatory diseases disclosed in the applied primary reference to Youssefyeh et al. At page 8 of the Examiner's Answer, the Examiner states that this argument was not deemed convincing "as inflammation can occur as a result of a wound, and thus, there is direct correlation between the two." The Examiner also states at the same page that the line of argument by Appellant "was not persuasive because scarring, such as keloid formation, can occur as a result of inflammation, either mild or intense". The Examiner's statement of correlation between inflammation and keloid formation, and

likewise, the equivalence between the treatment of inflammatory disease such as in the applied primary reference and the treatment of scars as claimed is grossly inaccurate. While, indeed, inflammation may be the cause of skin wounds, skin can be damaged in many other ways. However, the treatment of an inflammatory disease has absolutely nothing to do with the remodeling of the skin after the skin has healed. Even if healed improperly, as in keloids, the underlying cause is gone. The present invention is designed to remodel the skin after the skin has healed. Whatever the cause of the wound, after healing, the cause of the wound no longer exists. The primary reference is directed to the treatment of inflammation and disease in which inflammation is a present symptom of the disease. The claimed invention is directed to the treatment of collagen formation, including excessive collagen formation, not inflammation.

The Examiner further states on page 8 of the Examiner's Answer that "the Lee secondary reference vividly demonstrates the correlation between inflammation and scarring, and demonstrates that it is well known to simultaneously treat inflammatory conditions as well as scars, such as keloids, using the methods of scar treatment." Appellant argues herein that the Examiner is misreading Lee as Lee does not remotely describe the equivalence between the treatment of scars and the treatment of inflammatory diseases. At column 2, lines 40-67, Lee proposes three stages of the wound healing process. The Lee reference states that the first stage is an inflammatory stage. However, this stage is not directed to a healed wound, but is directed to the initial stage of the healing process. Lee describes the inflammatory stage as an "intensely degradative phase". The present invention is concerned with the opposite of a degradation stage and is unrelated to the inflammatory stage mentioned by Lee.

The claimed invention is directed to treating healed wounds and to reduce scarring or improve the appearance of scars. The Appellant's claimed process begins well into stage two of Lee's proposed healing process, in which the skin is being remodeled. Remodeling of skin is not an inflammatory process, but a process of collagen layering. Thus, Lee does not provide, as the Examiner's states, a correlation between the treatment of healed wounds and scars with the treatment of inflammatory diseases, such as specifically described in the primary reference.

At the bottom of page 8 of the Examiner's Answer, the Examiner states that "Lee further explicitly teaches the use of vitamin E, and teaches that cells that synthesize collagenase are influenced to a great extent by the environment in which they live. Lee teach that this includes cells of connective tissue and migratory cells that accumulate as a result of injury, inflammation or a immune phenomena." What this passage teaches is that inflammatory cells are among the many types of cells that can make collagenase. This passage does not remotely teach or suggest the equivalence between treating a disease which has inflammatory symptoms and the treating of a healed wound, such as scars. The treatment of healed wounds and the treatment of scarring to reduce scarring are directed to increasing collagenase and reducing the layer of collagen which is formed. This latter phenomenon is not the treatment of inflammation. Accordingly, Appellant strongly asserts that there is no reason to combine the elements of the composition disclosed in Youssefyeh, which teaches a composition for the treatment of inflammation and pain with elements of the compositions disclosed in Lee, which teaches a composition for treating scar tissue.

**(2) Whether the Examiner properly rejected claim 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Lee (U.S. Pat. No. 5,552,162).**

No additional arguments are needed, and Appellant stands on his Appeal Brief to illustrate that the rejection is improper.

Date: June 10, 2009

Respectfully submitted,  
/Stuart D. Frenkel/  
Stuart D. Frenkel  
Reg. No. 29,500  
Frenkel & Associates, P.C.  
3975 University Drive, Suite 330  
Fairfax, VA 22030  
Telephone: (703) 246-9641  
Facimile: (703) 246-9646